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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/668,558

09/22/2000

Frances Yen

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06/30/2005

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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,558

Applicant(s)

YEN ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/12/2001, 5/4/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group XI, claims 22, 23 and 25-28 in the reply filed on 3/4/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant points out that claim 20 of the instant application should be included with Group IX. This is found persuasive and Claim 20 would be included in the Group IX for the future examination. Further, in response to the restriction requirement mailed on 3/13/2002, Applicant failed to elect a polypeptide sequence as pointed out on page 6 of the Office Action, under subtitle Further Restriction. As a follow up to comply with the Restriction requirement, a telephone call was placed on 3/30/2005 to contact Attorney Eisenschenk. Applicant made a telephone election of the polypeptide sequence of SEQ ID NO: 32 that will read on the elected Group XI.

The requirement is deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1-28 are pending. Claims 1-21 and 24 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 22, 23, and 25-28 are examined on the merit to the extent that they read on the elected polypeptide sequence of SEQ ID NO: 32.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The instant application claims priority to U.S. Provisional Application No. 60/155,506 filed on 9/22/1999. However, the elected polypeptide sequence of SEQ ID NO: 32 is not disclosed in the U.S. Provisional Application. Therefore, priority of the instant application is the filing date of the instant filing date that is 9/22/2000.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example, page 79, line 6-7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below:

Applicant discloses many nucleotide and amino acid sequences through out the specification such as on page 86, lines 9 and 10, which are not in the sequence list and

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even if they are in the list, they do not have a sequence identity number and therefore, can not be checked in a list of 78 pages of sequence. As per 37 CFR 1.821 through 1.825 requirement each polypeptide with 4 amino acid and longer or a polynucleotide of 10 nucleic acid or longer should precede with an identifier.

Claim Objections

Claims 22 and 25 are objected for depending from claims of a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23, and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claimed invention is drawn to a method of selecting a compound useful for the treatment or prevention of an obesity related disease or disorder comprising contacting a recombinant cell comprising a polynucleotide that encodes a zinc finger protein comprising a DNA binding domain that binds specifically to 18 nucleotides sequence and that is at least 50% homologous to the SEQ ID NO: 1.

To provide undisclosed possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics for the invention. The factors to be considered include disclosure of complete functional characteristics, function correlation, method of making an invention, method of treatment, or any combination thereof. The instant application discloses that a zinc finger protein can bind to an 18 nucleotide sequence comprising two fragments of 9 nucleotides. Applicants do not provide "a 18 nucleotide sequences". As such a polynucleotide with 50% homology to the sequence ID NO: 1 encompasses innumerable sequences, and further, there exists a huge number of 18 nucleotide sequences that can be in fragments of 9 nucleotides each which can be separated by 0, 1, 2 or 3 nucleotides. Thus, the claims are drawn to a genus of innumerable nucleotide sequences homologous to the SEQ ID NO: 1 and a genus of huge number of 18 nucleotide sequences.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement

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that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

As discussed above, the skilled artisan cannot envision the detailed underlying mode of making innumerable possible mutations of the polynucleotide sequence of SEQ ID NO: 1, and many 18 nucleotide sequences to which a zinc finger protein with a 50% homology to the SEQ ID NO: 1 can bind, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of achieving it.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 22, 23 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of for selecting a compound for the treatment of obesity, would still not reasonably provide enablement

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for (i) treatment any obesity related disorder or disease and for prevention of obesity, and (ii) a zinc finger protein with 50% homology to the polynucleotide sequence of SEQ ID NO: 1 that can bind to any 18 nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The Nature of Invention: The claimed invention is drawn to a method of selecting a compound useful for any obesity related disorder or the prevention of obesity comprising contacting a recombinant cell comprising a polynucleotide that encodes a zinc finger protein that can bind to a 18 nucleotide sequence with 50% homology to the polynucleotide sequence of SEQ ID NO: 1 that can modulate an activity of lipolysis stimulated receptor (LSR) and the expression LSR.

The state of the prior art and the predictability or lack thereof in the art. The problem of predicting obesity is very complex because obesity is a polygenic disease that involves many factors such as genetics, environment and message signaling system. As Bays (Obesity Res. 12: 1197-1210, 2004) says that studies in anti-obesity research are in such a state of infancy, it is difficult to determine which of the single treatment targets, or which combination of treatment targets, has the potential to manage the worldwide epidemic of obesity. To date many agents have been tried in the area of CNS/ leptin/ gastrointestinal-neural/ endocrine pathways to reduce obesity in some subjects but not in all. Bays further says that a number of agents have been used to reduce or treat obesity in subjects, but due to complexity of the disease it would be impossible to predict at this point which agent or agents will eventually prove to

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revolutionize obesity treatment. Preventing obesity is even less predictable because even if one finds a compound that can treat an obese subject or obesity related disease still one would not be able to prevent it from happening again. Furthermore, one has to predict a person who is going to be obese based on genetic background, which is at its infancy and then gene and environment interaction. This is highly unpredictable because there are many genes and protein modifications that play important roles that could lead into obesity or an obesity related disorder.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to practice the invention commensurate in scope with the claims. These teachings are absent. Applicant's hypothesis is that a zinc finger binding protein could inhibit LSR activity or LSR gene expression to such an extent that one could use it for the prevention of obesity or an obesity-related disorder. However, even if this hypothesis works, it will require huge number of experimentation to screen innumerable zinc finger proteins and a huge number of 18 nucleotide sequences with 50% homology to the polynucleotide of SEQ ID NO: 1, to which a zinc finger protein can bind, and then one that works on in cell based assay would require in vivo testing. There is no working example present in the specification showing a zinc finger protein found as a result of screen can treat or prevent an obesity related disorder.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass a method of selecting a compound for the prevention of an

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obesity related disease or disorder, the lack of direction/guidance presented in the specification regarding which functional features are required in order to treat or prevent an obesity related disease, the absence of working examples directed to same, the complex nature of invention, the state of prior art which establishes unpredictability of the method that can screen a compound to modulate a LSR activity to such an extent to treat or prevent an obesity related disease, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 23, and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, the phrase "as a means" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 22, 23, and 25-28, the phrase "an activity of the LSR" renders the claim indefinite because in absence of definition, it is unclear what activity is referred as a LSR activity except that on page 7, lines 26-29, suggest that LSR is involved in the partitioning of dietary lipids between the liver and peripheral tissues, including muscle and adipose tissues.

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Conclusion

No claim is allowed.

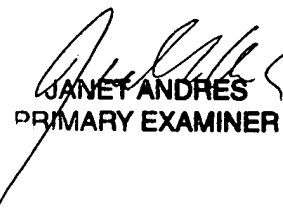
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
15 June 2005


JANET ANDRES
PRIMARY EXAMINER